K112541

Greatbatch Medical

FEB - 7 2012

510(k) Summary

1.0 Applicant Information

Applicant:	Greatbatch Medical
Facility Establishment Registration Number:	2183787
Submitter:	Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN 55441 (763) 951-8181 (Phone) (716) 759-5040 (Fax)
Contact Person:	Sara Bakker
Date Prepared:	August 31, 2011

2.0 Device Information

Trade Name:	Z°Flex-270™ Steerable Sheath
Common Name:	Steerable Catheter
Classification Name:	Catheter, Steerable
Product Code:	DRA
Regulation:	Class II 21 CFR 870.1280
Classification Panel:	Cardiovascular

3.0 Predicate Device

The subject device is equivalent to the following device:

- K102176 - Medtronic FlexCath Steerable Sheath and Dilator

4.0 Description of Device

The Z°Flex-270™ Steerable Sheath is a 12 Fr percutaneous steerable sheath with a flexible tip designed for gaining access to the vasculature including the coronary systems. It is comprised of two (2) main sections: the shaft and the handle. The Z°Flex-270 Steerable Sheath has uni-directional adjustable tip geometry with a rotating mechanism on the handle used to control sheath deflection. A dilator and guidewire are included with each kit.

5.0 Indications for Use

The Z°Flex-270™ Steerable Sheath is indicated for use to facilitate transvenous introduction of diagnostic/therapeutic catheters into the vasculature and into the chambers of the heart.

6.0 Predicate Device Comparison / Technological Characteristics

The Z°Flex-270™ Steerable Sheath has similar indications for use, technological characteristics and identical principles of operation compared to the predicate Medtronic FlexCath Steerable Sheath (*K102176*). Z°Flex-270 indications for use differ from FlexCath in that Z°Flex-270 is intended for venous access only. Z°Flex-270 also differs slightly in the design of the deflection mechanisms and includes a guidewire, provided for convenience in the steerable sheath kit for convenience. Performance (bench) testing and biocompatibility testing were performed to demonstrate that the proposed device performs as intended and does not raise new questions of safety or efficacy compared to the predicate device.

7.0 Description of Safety and Substantial Equivalence

To verify that the Z°Flex-270™ Steerable Sheath design met its functional and performance requirements, representative finished, sterilized samples of the subject device underwent the following testing, biocompatibility, sterilization, packaging, mechanical testing and shelf-life testing in accordance with applicable industry standards and FDA guidance.

Testing included:

- Sterilization testing per ISO 11135-1
- Shelf Life
- Packaging
- Performance (Bench) testing:
  - Visual
  - Dimensional
  - Functional
    - Hemostasis valve leak testing (per ISO 11070)
    - Deflection testing
    - Air aspiration and hemostasis
    - Fatigue testing (deflection)

- Sheath tip robustness testing after multiple catheter deployment/retractions
- Kink resistance
- Torque
- Tensile testing
- Dilator to sheath retention
- Guidewire testing per ISO 11070

Biocompatibility testing for the subject device included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Materials Mediated Rabbit Pyrogen
- Hemolysis
- Partial Thromboplastin Time
- Platelet and Leukocyte Counts
- Complement Activation
- Thrombosis (*In-vivo)* – 4 hour contact
- Testing for Latex, DEHP, and Bisphenol A

Conclusion: Test results demonstrate that the Z°Flex-270 Steerable Sheath met all specifications per functional and performance requirements. The device performs as intended and does not raise any new questions of safety or efficacy.

8.0 Statement of Equivalence

The Z°Flex-270 Steerable Sheath has similar indications for use, technological characteristics and identical principles of operation compared to the predicate Medtronic FlexCath Steerable Sheath. Based on these similarities, in addition to the results from safety and performance testing, Z°Flex-270 Steerable Sheath is considered substantially equivalent to the Medtronic FlexCath Steerable Sheath (*K102176*).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 7 2012

Greatbatch Medical
c/o Ms. Sara Bakker
Senior Regulatory Affairs Specialist
2300 Berkshire Lane N
Minneapolis, MN 55441

Re: K112541
Trade Name: Z°Flex-270™ Steerable Sheath
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: II (two)
Product Code: DRA
Dated: November 30, 2011
Received: December 1, 2011

Dear Ms. Bakker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use Statement

510(k) Number (if known): K112541

Device Name: Z°Flex-270™ Steerable Sheath

Indications for Use:

The Z°Flex-270™ Steerable Sheath is intended to facilitate transvenous introduction of diagnostic/therapeutic catheters into the vasculature, and into the chambers of the heart.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112541